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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,023	12/11/2003	Anne Vanet	1421-03	2355

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EXAMINER	
SKOWRONEK, KARLHEINZ R	
ART UNIT	PAPER NUMBER
1631	
MAIL DATE	DELIVERY MODE
05/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,023	VANET ET AL.	
	Examiner	Art Unit	
	Karlheinz R. Skowronek	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim1-10 and 20-29, drawn to method for identifying a motif, classified in class 702, subclass 20.

II. Claim 11, drawn to an influenza Vaccine, classified in class 424, subclass 206.1.

III. Claim 12, drawn to an HIV vaccine, classified in class 424, subclass 207.1.

IV. Claim 13, drawn to a Hepatitis C vaccine, classified in class 424, subclass 228.1.

V. Claim 14, drawn to a pharmaceutical composition for influenza treament, classified in class 530, subclass 300.

VI. Claim 15, drawn to pharmaceutical composition for HIV treatment, classified in class 530, subclass 300.

VII. Claim 16, drawn to pharmaceutical composition for pharmaceutical composition for Hepatitis C treatment, classified in class 530, subclass 300.

VIII. Claim 17, drawn to a method of treating influenza, classified in class 514, subclass 2.

IX. Claim 18, drawn to a method of treating HIV, classified in class 514, subclass 2.

X. Claim 19, drawn to a method of treating Hepatitis C, classified in class 514, subclass 2.

XI. Claim 30, drawn to a method of preparing oligonucleotides, classified in class 536, subclass 25.3.

XII. Claim 31, drawn to a method of preparing polypeptides, classified in class 530, subclass 333.

The inventions are distinct, each from the other because of the following reasons:

Inventions group I and groups XI-XII are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have different effects. For example the invention of group I results in the identification of a motif, whereas the method of group XI results in the production of an oligonucleotide. The method of group XII is distinguished from group I as it also has produces a different result, i.e. the production of a polypeptide. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions of groups II-IV and groups V-VII are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable

of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are drawn to two super groups Vaccines, groups II-IV, and pharmaceutical compositions, groups V-VII. The group of vaccines is distinct from the group of pharmaceutical compositions because the vaccines have a different mode of operation from the pharmaceutical compositions. The groups of vaccines do not overlap in scope with the pharmaceutical compositions be cause the pharmaceutical compositions can be used in gene therapy treatments where the vaccines can only be used in a immune stimulatory related manner. Furthermore the groups of vaccines are distinct from each other because they are directed to different diseases and have different distinct molecular structures. Similarly, the groups of pharmaceutical compositions are distinct from one another because they are directed to different diseases and have different distinct molecular structures.

Inventions groups VIII-X and methods of group I and groups XI-XII are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). The methods of treatment of groups VIII-X are distinct from the methods of group I and groups XI-XII, because the method of treatments have different outcomes and different steps from the methods of group I and groups XI-XII. The methods of treatment also do not overlap in

scope with the methods of group I and groups XI-XII because the method of treatment will not produce the motifs, polypeptides or oligonucleotides of groups. Additionally, the inventions of groups VIII-X are distinct from each other, because the method of treating HIV (group IX), for example, will not treat influenza (group VIII). The method of treatment between each of the groups would also require the administration of different therapeutically effective amounts distinguishing the methods of treating further.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, because the inventions require a different field of search (see MPEP § 808.02), and because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Species election

If Group I is elected a further species election is required:

This application contains claims directed to the following patentably distinct species: A. Sequences of step (a)

Ai. Sequence related to the protease of HIV, claim 20;

Aii. Sequences related to the reverse transcriptase of HIV, claim 21;

Aiii. Sequences related to the integrase of HIV, claim 22;

Aiv. Sequence related to the neuraminidase flu, claim 23;

Av. Sequence related to the hemeagglutinin of flu, claim 24;

Avi. The Hepatitis C genome, claim 25;

Avii Sequence related to the HspA of *H. pilori*, claim 26;

Aviii Sequence related to the hemeagglutinin adhesin of *E. coli*, claim 27.

The species are independent or distinct because each of the species have a different chemical structure.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-10 and 28-29 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karlheinz R. Skowronek whose telephone number is (571) 272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karlheinz R. Skowronek/

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER